

## **Positive Phase II Results with BSI-201 (Iniparib) in Women with Metastatic Triple Negative Breast Cancer Published in *The New England Journal of Medicine***

**Paris, France – January 5, 2011** – Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) and its wholly owned subsidiary, BiPar Sciences, today announced that The New England Journal of Medicine (NEJM) published the final Phase II data for the investigational drug BSI-201 (iniparib\*) demonstrating significant clinical benefit in women with metastatic triple negative breast cancer (mTNBC) when BSI-201 (iniparib) was administered in combination with chemotherapy agents gemcitabine/carboplatin. Although not a pre-specified endpoint, overall survival also was significantly increased in women who received BSI-201 (iniparib).

The study, "*Iniparib plus Chemotherapy in Metastatic Triple-Negative Breast Cancer*," was published in the January 5, 2011 online version of *The New England Journal of Medicine* and will be published in the January 20, 2011 print edition. These findings were presented at the 35<sup>th</sup> European Society for Medical Oncology (ESMO) Congress in Milan, Italy.

*"These published data show that the addition of iniparib to gemcitabine and carboplatin provided a significant improvement in clinical benefit in women with metastatic triple negative breast cancer, an aggressive form of breast cancer with no approved standard treatments that target this particular tumor subtype,"* said Joyce O'Shaughnessy, M.D., lead investigator of the study and co-chair of the Breast Cancer Research Program at the Baylor-Charles A. Sammons Cancer Center, Texas Oncology, U.S. Oncology in Dallas.

According to the study results, 56 percent of patients in the BSI-201 (iniparib) group showed a clinical benefit – defined as a complete or partial response or stable disease of at least six months – compared with 34 percent ( $p=0.01$ ) of patients in the chemotherapy group alone. Median progression-free survival in the BSI-201 (iniparib) group was 5.9 months compared with 3.6 months in the chemotherapy group (95% CI (0.39-0.90) HR=0.59,  $p=0.01$ ). The overall response rate was 52 percent in the BSI-201 (iniparib) group versus 32 percent ( $p=0.02$ ) in the chemotherapy group alone. Although it was not a pre-specified endpoint of the trial median overall survival among women who received BSI-201 (iniparib) was 12.3 months, compared with 7.7 months among women who received chemotherapy alone – translating to a 43 percent reduction in the risk of death (95% CI, (0.36-0.90) HR=0.57,  $p=0.01$ ).

In the phase II BSI-201 (iniparib) study, the most common any grade adverse events in the BSI-201 (iniparib) arm were neutropenia, anemia, thrombocytopenia, fatigue/asthenia, nausea and constipation. The most common grade 3/4 adverse events in the BSI-201 (iniparib) treatment arm were neutropenia, anemia, thrombocytopenia, leukopenia and fatigue/asthenia. There were two fatal adverse events (3.4%) in the chemotherapy-alone group and three (5.3%) in the BSI-201 (iniparib) group, all attributed to disease progression within 30 days of receiving study treatment. A large phase III study is ongoing and results are expected in 2011.

\* *Iniparib is the United States Adopted Name (USAN) for the investigational agent BSI-201.*

### **About the Phase II BSI-201 (Iniparib) Study**

This multicenter, open-label, randomized study included 123 women with mTNBC. The primary endpoints were safety and tolerability and clinical benefit rate of BSI-201 (iniparib), defined as a complete or partial response or stable disease of at least six months. Secondary endpoints included overall response rate and progression-free survival. Overall survival was also assessed, although it was not a pre-specified endpoint of the trial. Patients received gemcitabine and carboplatin alone (chemotherapy group) or in combination with BSI-201 (iniparib) until disease progression or unacceptable toxicity. Patients in the chemotherapy group whose disease progressed were allowed to cross over to the BSI-201 (iniparib) plus chemotherapy group. Efficacy analyses were conducted on the intent-to-treat (ITT) population.

### **About BSI-201 (Iniparib)**

BSI-201 (iniparib) is a novel investigational anti-tumour agent with poly (ADP-ribose) polymerase (PARP) inhibitory activity.

BSI-201 (iniparib) is in phase III trials for patients with mTNBC and squamous non-small cell lung cancer, as well as in phase II trials for patients with ovarian, uterine and brain cancers.

The U.S. Food and Drug Administration (FDA) granted Fast Track designation to iniparib for mTNBC. The regulatory submissions are planned for Q1 2011 in the United States and Q2 2011 in the European Union.

### **About Triple-Negative Breast Cancer (TNBC)**

When patients are diagnosed with breast cancer, their tumors are routinely tested for the presence of estrogen and progesterone receptors and for the over-expression of HER2. However, 15 to 20 percent of all breast cancers lack over-expression of all three proteins – giving rise to the term “triple negative breast cancer” or TNBC. Research has shown TNBC can be difficult to treat, leading the disease to be associated with poorer outcomes than other types of breast cancer. Women with TNBC are not candidates for hormonal therapy such as tamoxifen or the targeted therapy Herceptin, leaving chemotherapy as the standard treatment.

### **About sanofi-aventis Oncology**

Sanofi-aventis Oncology is targeting cancer on all fronts in an effort to address unmet medical needs for a broad range of patients. Starting with a deep understanding of the mechanisms by which cancer develops, grows and spreads, as well as identifying the right science early in the discovery process, the company employs innovative approaches to bring the right medicines to the right patients. There are currently more than 10 compounds in development across a broad scientific platform, including cytotoxic, antimitotic, anti-angiogenic agents, antivascular agents, monoclonal antibodies and cancer vaccines, as well as supportive care therapies. Four of these compounds are now being investigated in Phase III clinical studies aimed at multiple solid and hematologic tumors.

### **About sanofi-aventis**

Sanofi-aventis, a leading global pharmaceutical company, discovers, develops and distributes therapeutic solutions to improve the lives of everyone. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY). For more information, please visit [www.sanofi-aventis.com](http://www.sanofi-aventis.com).

### **About BiPar Sciences**

BiPar Sciences is a biopharmaceutical organization dedicated to pioneering novel tumor-selective therapies designed to address urgent unmet needs of cancer patients. Located in South San Francisco, California, BiPar is a wholly owned subsidiary of sanofi-aventis. For more information, please visit [www.biparsciences.com](http://www.biparsciences.com).

### **Forward Looking Statements**

*This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words “expects,” “anticipates,” “believes,” “intends,” “estimates,” “plans” and similar expressions. Although sanofi-aventis’ management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of sanofi-aventis, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of such products candidates, the absence of guarantee that the products candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group’s ability to benefit from external growth opportunities as well as those discussed or identified in the public filings with the SEC and the AMF made by sanofi-aventis, including those listed under “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” in sanofi-aventis’ annual report on Form 20-F for the year ended December 31, 2009. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.*

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